



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/524,864	06/23/2005	Frederick L. Coe	80337.0018 US	2996
41913	7590	07/16/2007		
HOGAN & HARTSON L.L.P. 875 THIRD AVENUE NEW YORK, NY 10022			EXAMINER HOPKINS, CHRISTINE D	
			ART UNIT 3735	PAPER NUMBER
			MAIL DATE 07/16/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/524,864

Applicant(s)

COE, FREDERICK L.

Examiner

Christine D. Hopkins

Art Unit

3735

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 April 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 17-21 is/are allowed.
- 6) ☒ Claim(s) 1-16 and 22-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This Office Action is responsive to the Amendment filed 16 April 2007. Claims 1-24 are now pending. The Examiner acknowledges the amendments to claims 1, 9, 17 and 22.

Claim Rejections - 35 USC § 101

2. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

3. Claim 9 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 9 at line 2 recites "wherein said outlet is in fluid communication with the peritoneal cavity of the patient." The positive recitation of a part of the human body renders the claim non-statutory. The examiner suggests amending the claim to read --wherein said outlet is adapted to be in fluid communication with the peritoneal cavity of the patient--.

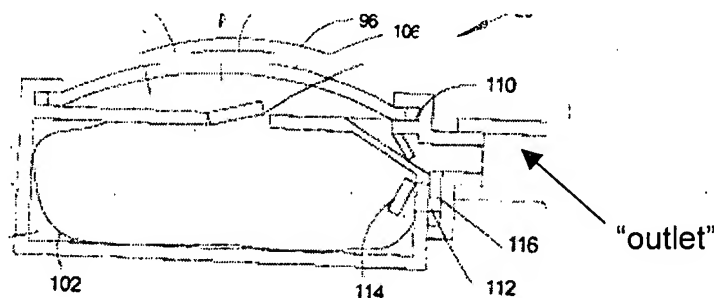
Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1-4, 6, 9-16 and 22-24 are rejected under 35 U.S.C. 102(e) as being anticipated by Meah (U.S. Patent No. 6,432,040). Meah discloses an implantable sphincter capable of surround the stomach of a patient. Regarding claims 1 and 22-24, Meah teaches an adjustable band to be placed over the first part of the stomach adjoining the esophagus. The band has an internal inflation chamber to be increased or decreased thereby adjusting the tightness of the device (col. 2, lines 15-21). The inflation device has a fluid reservoir for providing fluid to the inflatable chamber (col. 2, lines 47-50). A first valve **110** is between the fluid reservoir **102** and the inflatable chamber of the band (sphincter body comprising the adjustable band) for expanding the sphincter body (col. 6, lines 4-15 and Fig. 6). A second valve **114** is between the inflatable chamber and an "outlet" (see depiction below).



A "controller," or diaphragm **96** actuates the valves, thereby increasing or decreasing the amount of fluid introduced into the sphincter body for adjusting its opening and thus imposing a tighter fit on the organ. The reservoir is further capable of having a pressure that remains greater than or equal to the pressure in the inflatable chamber. The "controller" **96** is remotely controllable from outside the patient since the patient can physically press on the "controller" located under the skin of the patient (col. 6, lines 9-

15). In view of claim 2, the "remote control" is construed as the action of the patient pressing on the "controller" **96** located internal to the patient. Regarding claim 3, the "receiver" is construed as valve **106** since it receives control signals from the patient pressing the "controller" **96**. The "controller" **96** in turn, actuates valves **110** and **114** in response to the deflection of the diaphragm, or "controller" **96** by patient's external manipulation (col. 6, lines 5-15).

With reference to claims 4 and 6, Meah further teaches a power source for providing power to the controller in the form of a battery (col. 5, lines 41-44).

Regarding claim 10, the "outlet" as construed in claim 1, is also considered to be a "waste reservoir" since no further structure is provided in the claim language. In view of claim 11, since the fluid flows from an area of high pressure in the fluid reservoir **102** through valve **114** to the "outlet" (refer back to depiction above), the "waste reservoir," which constitutes the "outlet," is considered to be "negatively pressurized."

With respect to claims 12-14, the inflatable chamber **28** is coextensive with an inner stomach-facing surface **30** (col. 4, lines 20-22 and Fig. 3). The inflatable chamber **28** does not fold or wrinkle as a result of its inextensible outer surface **62**, rendering the inner surface substantially smooth (col. 4, lines 52-60 and Fig. 3).

Regarding claim 15, the band of Meah may further incorporate a filament **54** having teeth along one side for locking with receptacle **56** (col. 4, lines 41-46). In view of claim 16, the fluid that fills the sphincter body is a saline solution (col. 5, lines 21-23).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 5 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meah (U.S. Patent No. 6,432,040) in view of Dargent et al. (U.S. Patent No. 6,547,801). Meah discloses the invention as claimed, see rejection supra; however Meah fails to disclose the type of power source utilized. Dargent et al. (hereinafter Dargent) teach a constriction device for treating morbid obesity. Regarding claims 5 and 7, Dargent teaches an induction coil **36** located within the receiver **11** and connected to an electrolytic capacitor **39** to store, charge and provide power for the receiver to actuate and drive the motor **21** (col. 8, lines 17-33), which in turn, determines the degree of constriction of the device (col. 7, lines 37-40). Therefore, at the time of the invention, it would have been obvious to one having ordinary skill in the art to have employed an induction coil and a capacitor as taught by Dargent to power the constriction device of Meah that adjusts the degree of constriction on the stomach.

8. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Meah (U.S. Patent No. 6,432,040) in view of Dargent et al. (U.S. Patent No. 6,547,801) and further in view of Laub (U.S. Patent No. 5,944,751). The combination of Meah and Dargent disclose the use of a capacitor as a power source, see rejection supra;

Art Unit: 3735

however, the combination fails to teach that the capacitor is piezo-electrically charged. Laub discloses an implantable, electromechanical valve controlled by a power supply. Regarding claim 8, Laub teaches that the energy generated by movement of the valves supplies a small current through piezoelectric means to power an oscillator. Therefore, at the time of the invention, it would have been obvious to one having ordinary skill in the art to have supplied a capacitor as taught by the combination of Meah and Dargent with piezoelectric means for charging a capacitor as disclosed by Laub for generating charge to power an implantable device.

Allowable Subject Matter

9. Claims 17-21 are allowable over the prior art of record. The following is a statement of reasons for the indication of allowable subject matter: regarding claims 17-21, the prior art of record does not teach or suggest implanting a gastric banding device whereby control signals are remotely transmitted from outside a patient to the gastric banding device to actuate a first valve between a pressurized fluid reservoir and an inflatable chamber whereby the pressure in the pressurized fluid reservoir remains greater than or equal to the pressure in the inflatable chamber.

Response to Arguments

10. Applicant's arguments filed 16 April 2007 with respect to the rejection of claims 1-4, 6, 9-16 and 22-24 under 35 U.S.C. 102(e) citing Meah ('040) have been fully considered and are not persuasive. Applicant contends that Meah does not include a

passive reservoir and that power is only required when operating the valves, and only for short time intervals. However, this argument is not persuasive. The specification of the present invention provides no special technical definition for "a passive pressurized fluid reservoir for providing fluid to inflate said inflatable chamber...." The fluid reservoir **102** disclosed by Meah serves as a fluid reservoir for providing fluid to inflate said inflatable chamber. Furthermore, the fluid reservoir **102** is interpreted as a "passive pressurized" fluid reservoir since it is maintained at a pressure higher than its surroundings. Regarding the argument that power is only required when operating the valves, and only for short time intervals, such limitations are not required by the claim language set forth in independent claim 1. In view of the foregoing, the rejection of claims 1-4, 6, 9-16 and 22-24 under 35 U.S.C. 102(e) citing Meah ('040) is maintained.

11. Applicant's arguments filed 16 April 2007 with respect to the rejection of claims 17-21 under 35 U.S.C. 102(e) citing Meah ('040) have been fully considered and are persuasive. The rejection of claims 17-21 has been withdrawn.

12. Applicant's arguments filed 16 April 2007 with respect to the rejection of claims 5 and 7 under 35 U.S.C. 103(a) citing Meah ('040) in view of Dargent ('801) have been fully considered and are not persuasive. Applicant contends that Dargent does not supply the deficiency of Meah by disclosing a gastric constriction device employing a constricting flexible band or any use of a pressurized reservoir. However, this argument is not persuasive. Dargent does indeed disclose a gastric constriction device employing

Art Unit: 3735

a constricting flexible band (col. 3, lines 10-22) and the deficiency of Meah lies in the type of power source utilized for a constricting flexible band which Dargent expressly discloses. Therefore, the rejection of claims 5 and 7 under 35 U.S.C. 103(a) citing Meah ('040) in view of Dargent ('801) is maintained.

13. Applicant's arguments filed 16 April 2007 with respect to the rejection of claim 8 under 35 U.S.C. 103(a) citing Meah ('040) in view of Dargent ('801) and further in view of Laub ('751) have been fully considered and are not persuasive. Applicant contends that Laub also does not disclose a pressurized reservoir. However, the deficiency of the combination of Meah and Dargent lies in a piezoelectrically charged capacitor. Laub similarly discloses a medically implantable device, which may also be controlled and powered from a location exterior to the patient's body (col. 1, lines 51-59) as with the present invention and that of Meah and Dargent. Therefore, the rejection of claim 8 under 35 U.S.C. 103(a) citing Meah ('040) in view of Dargent ('801) and further in view of Laub ('751) is maintained.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine D. Hopkins whose telephone number is (571) 272-9058. The examiner can normally be reached on Monday-Friday, 7 a.m.-3:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

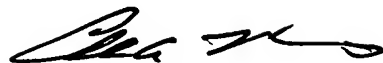
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information

Art Unit: 3735

system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

CDH

Christine D Hopkins
Examiner
Art Unit 3735



Charles A. Marmor, II
Supervisory Patent Examiner
Art Unit 3735